## BASIC CARE OMEPRAZOLE- omeprazole tablet, orally disintegrating, delayed release L. Perrigo Company

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#### **Amazon Omeprazole Drug Facts**

#### Active ingredient (in each tablet)

Omeprazole 20 mg

#### Purpose

Acid reducer

#### Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

#### Warnings

**Allergy alert:** do not use if you are allergic to omeprazole

#### Do not use if you have:

- trouble or pain swallowing food, vomiting with blood, or bloody or black stools
- heartburn with lightheadedness, sweating or dizziness
- chest or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**

These may be signs of a serious condition. See your doctor.

#### Ask a doctor before use if you have:

- had heartburn over 3 months. This may be a sign of a more serious condition.
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

#### Ask a doctor or pharmacist before use if you are

taking a prescription drug. Acid reducers may interact with certain prescription drugs.

#### Stop use and ask a doctor if:

- your heartburn continues or worsens
- you need to take this product for more than 14 days

- you need to take more than 1 course of treatment every 4 months
- you get diarrhea
- you develop a rash or joint pain

#### If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### Directions

- for adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect; some people get complete relief of symptoms within 24 hours

#### **14-Day Course of Treatment**

- take 1 tablet before eating in the morning
- do not crush or chew tablets
- place the tablet on tongue; tablet disintegrates, with or without water. The tablets can also be swallowed whole with water.
- take every day for 14 days
- do not take more than 1 tablet a day
- do not use for more than 14 days unless directed by your doctor
- do not take this medicine with alcohol

#### **Repeated 14-Day Course (if needed)**

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor before use. Heartburn in children may sometimes be caused by a serious condition.

#### Other information

- read the directions and warnings before use
- keep the carton. It contains important information.
- store at 20-25°C (68-77°F); keep product out of high heat and moisture

#### **Inactive ingredients**

amino methacrylate copolymer, ascorbic acid, cetyl alcohol, colloidal silicon dioxide, crospovidone, ferric oxide, flavor, hypromellose, hypromellose phthalate, maize maltodextrin, mannitol, microcrystalline cellulose, propylene glycol, silicon dioxide, sodium stearate, sodium stearyl fumarate,

sorbitol, sucralose, sugar spheres, talc, titanium dioxide, triethyl citrate

#### Questions or comments?

**1-800-719-9260:** weekdays 7:30 AM to 5:00 PM EST

#### Package/Label Principal Display Panel

 $MELTech^{TM}$ 

Melts In Your Mouth

Acid Reducer

FDA Approved

Compare to Prilosec OTC®

omeprazole

delayed release orally disintegrating tablets 20 mg

acid reducer

Melts in Your Mouth

Dissolves Without Water

Strawberry Flavor

orally disintegrating tablets

actual size

Treats Frequent Heartburn!

24 HR

14 TABLETS

one 14-day courses of treatment

May take 1 to 4 days for full effect



Safety Feature -Do not use if printed tablet blister unit is open or torn.





Acid Reducer

FDA Approved

NDC 0113-7520-74

Compare to Prilosec OTC<sup>6</sup>

# omeprazole

delayed release orally disintegrating tablets 20 mg acid reducer

**Melts in Your Mouth Dissolves Without Water** 

Strawberry Flavor



disintegrating tablets actual size

Treats Frequent Heartburn!

24 HR

14 TABLETS

one 14-day course of treatment May take 1 to 4 days for full effect

\*This product is not manufactured or distributed by Procter & Gamble, distributor of Prilosec OTC®.

> Distributed by: Perrigo Allegan, MI 49010

Made in Israel

Tips for Managing Heartburn

#### **BASIC CARE OMEPRAZOLE**

omeprazole tablet, orally disintegrating, delayed release

# Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:0113-7520 Route of Administration ORAL

## Active Ingredient/Active Moiety Ingredient Name Basis of Strength OMEPRAZOLE (UNII: KG60484QX9) (OMEPRAZOLE - UNII:KG60484QX9) OMEPRAZOLE OMEPRAZOLE 20 mg

Inactive Ingredients	
Ingredient Name	Strength
DIMETHYLAMINO ETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960 MK)	

FERRIC OXIDE RED (UNII: 1K09F3G675)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MANNITOL (UNII: 3OWL53L36A)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STEARATE (UNII: QU7E2XA9TG)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	

Product Characteristics					
Color	RED (reddish)	Score	no score		
Shape	ROUND	Size	9mm		
Flavor	STRAWBERRY	Imprint Code	20		
Contains					

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:0113-7520-55	3 in 1 CARTON	08/30/2018		
1		14 in 1 CARTON			
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:0113-7520-74	14 in 1 CARTON	10/17/2018		
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NDA	NDA209400	08/30/2018		

### Labeler - L. Perrigo Company (006013346)

Revised: 4/2019 L. Perrigo Company